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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,864	03/13/2002	John M. Barker	1032-P02467US1	4471

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EXAMINER	
MAYNARD, JENNIFER J	

ART UNIT	PAPER NUMBER
3763	10

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,864	BARKER ET AL.	
	Examiner	Art Unit	
	Jennifer J Maynard	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *33-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,10,11,13-16,18-20,22-26,28-32,54,57 and 60* is/are rejected.

7)☒ Claim(s) *5-7,9,12,17,21,27,55,56,58 and 59* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4 & 5*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 33-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Applicant's election without traverse of Species I, Figures 1-8 in Paper No. 9 is acknowledged.

Claim Objections

Claim 57 is objected to because of the following informalities: In line 2, the word "assemble" should be --assembly--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 13, 15, 16, 54, 57 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Botich et al. (US 6,039,713 B1).

1-Botich et al. discloses a pre-filled retractable needle injection device, as recited in Claims 1, 2, 13, 15 and 16, comprising a hollow barrel (20); a socket (35) associated with the

barrel configured to receive the vial (85); a needle (15) having a sharpened tip operable between an exposed position (shown in Figures 1A, 1B and 2) in which the sharpened tip projects forwardly from the barrel and a shielded position (shown in Figure 1C) in which the sharpened tip is shielded from contact; and a transfer chamber (50) within the barrel for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle; wherein after use, the needle is disposed in the shielded position; a transfer conduit (17) configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber; a pierceable rear seal (90) adapted to provide a fluid-tight seal between the vial and the transfer chamber; a biasing element (40) biasing the needle toward a shielded position; and a needle retainer (60) releasably retaining the needle in the exposed position against the bias of the biasing element.

2-Botich et al. discloses a pre-filled retractable needle injection device, as recited in Claims 54, 57 and 60, comprising a housing (20) cooperable with the needle assembly (15); a socket (35) for receiving the container (85); a pressurizing element (90) within the housing to provide positive fluid pressure within the container when the container is disposed in the socket; a chamber (50) in the housing for receiving the medicinal fluid from the container; wherein the housing has an activation surface (65) cooperable with the needle assembly and adapted to activate retraction of the needle after use; a fluid path (17) extending between the container and the needle assembly when the needle assembly is attached to the housing and the container is disposed in the socket; a stop (60) for releasably retaining the housing from displacement relative to the needle assembly when the needle assembly is connected with the housing.

Claims 1-4, 8, 11, 13-15, 19, 20, 22, 24-28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Knauer (US 6,607,508 B2).

1-Knauer discloses a vial injector device, as recited in Claims 1-4, 8, 11, 13-15, comprising a hollow barrel (400, 401); a socket (B, see labeled Figure below) associated with the barrel configured to receive the vial (100); a needle (201) having a sharpened tip operable between an exposed position (shown in Figures 8 and 9) in which the sharpened tip projects forwardly from the barrel and a shielded position (shown in Figures 1, 6 and 7) in which the sharpened tip is shielded from contact; and a transfer chamber (D, see labeled Figure below) within the barrel for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle; wherein after use, the needle is disposed in the shielded position; a transfer conduit (C, see labeled Figure below) configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber; a vial holder (A, see labeled Figure below) engaging the barrel, wherein the socket is formed in the vial holder; the vial holder is at least partially disposed within the barrel; a piston (303) for expelling medicine out of the transfer chamber through the needle; a valve (304) adapted to control the flow of fluid between the transfer chamber and the vial; a pierceable rear seal (102) adapted to provide a fluid-tight seal between the vial and the transfer chamber; a pierceable forward seal (305) providing a fluid-tight seal between the transfer chamber and the needle; and a biasing element (405, see Figure 7) biasing the needle toward a shielded position.

2-Knauer discloses a vial injector device, as recited in Claims 19, 20, 22, 24-28, 30 and 31, comprising a vial (100) containing a quantity of medicinal fluid, wherein the vial comprises a container (100) having a fixed rearward wall (E, see labeled Figure below) and a fixed pierceable

wall (102) sealing the forward end; a holder (A, B, see labeled Figure below) configured to receive the vial; an injection needle (201) for expelling the medicinal fluid from the device wherein the injection needle comprises a sharpened tip operable between an extended position (shown in Figures 8 and 9) in which the sharpened tip is exposed for use and a protected position (shown in Figures 1, 6 and 7) in which the sharpened tip is shielded to prevent inadvertent contact with the sharpened tip; and a communication path (C, D, see labeled Figure below) adapted to establish fluid flow between the vial and the injection needle to allow the medicinal fluid to flow from the vial to the injection needle; wherein after use the needle is disposed in the protected position; a biasing element (405, see Figure 7) biasing the needle toward the retracted position; a chamber (D, see labeled Figure below) for receiving the medicinal fluid from the vial, wherein the medicinal fluid is subsequently expelled from the chamber though the injection needle; a conduit (C, see labeled Figure below) between the vial and the chamber; the chamber is disposed in a first housing (302); a pierceable seal sealing an end of the chamber (305); a second housing (400, 401) associated with the injection needle, wherein the first housing is displaceable relative to the second housing; a stop (no reference numeral, described in Column 4, lines 17-23) for releasably impeding relative displacement between the first and second housings; and a valve (304) controlling the flow of medicinal fluid from the chamber.

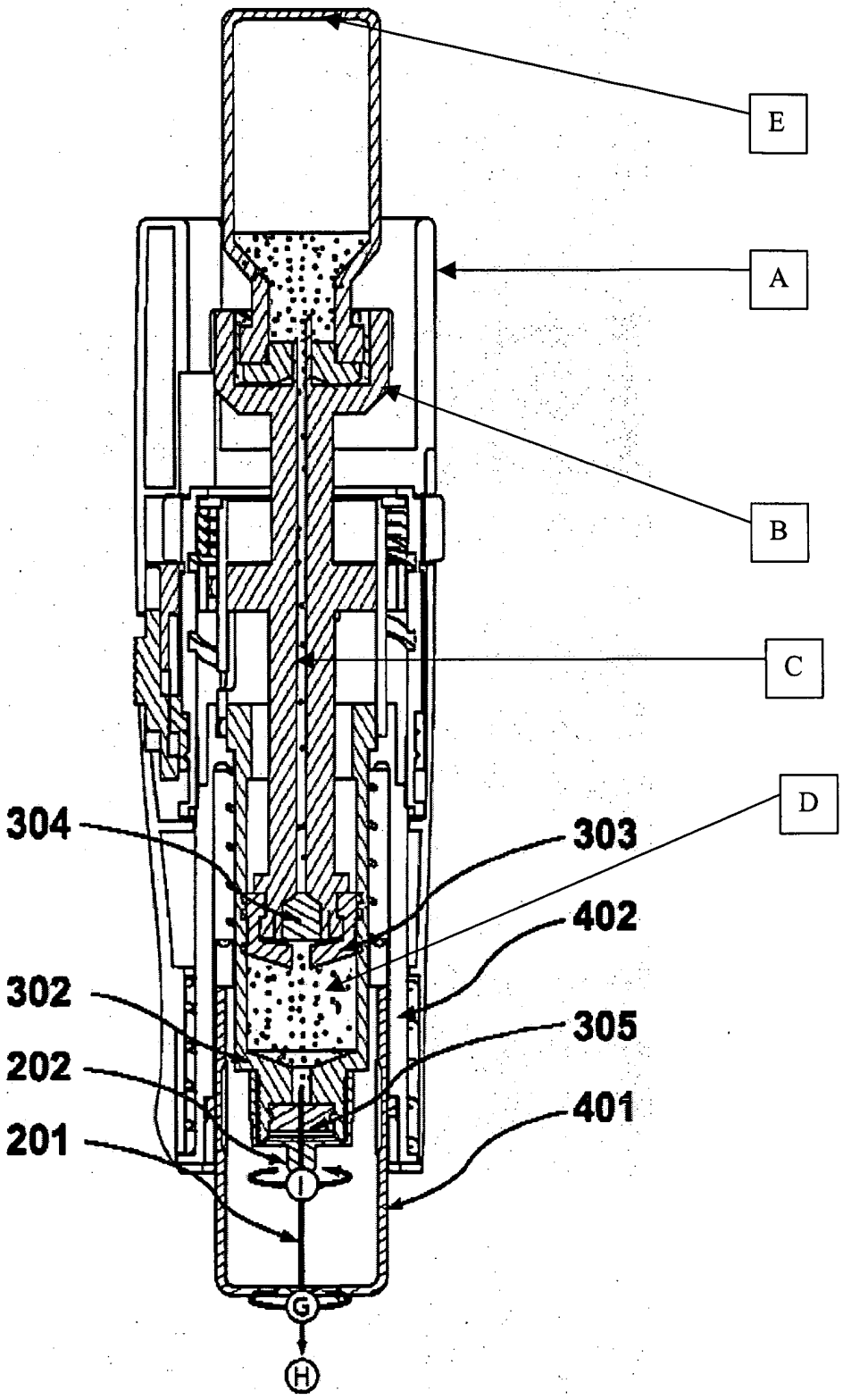

FIGURE 6

Claims 1-3, 8, 10, 11, 13, 15, 18-20, 22-26, 28-30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Lavi et al. (US 6,364,865 B1).

1-Lavi et al. discloses a drug delivery system, as recited in Claims 1-3, 8, 10, 11, 13, 15 and 18, comprising a hollow barrel (A, see labeled Figure below); a socket (B, see labeled Figure below) associated with the barrel configured to receive the vial (632); a needle (664) having a sharpened tip operable between an exposed position (shown in Figure 28C) in which the sharpened tip projects forwardly from the barrel and a shielded position (shown in Figures 28A and 28B) in which the sharpened tip is shielded from contact; and a transfer chamber (652) within the barrel for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle; wherein after use, the needle is disposed in the shielded position; a transfer conduit (644, 644A) configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber; a piston (650) for expelling medicine out of the transfer chamber through the needle; wherein the transfer chamber is displaceable relative to the needle; a valve (638) adapted to control the flow of fluid between the transfer chamber and the vial; a pierceable rear seal (C, see labeled Figure below) adapted to provide a fluid-tight seal between the vial and the transfer chamber; a biasing element (D, labeled Figure below) biasing the needle toward a shielded position; and a piston operable to pump air into the vial to pressurize the fluid in the vial.

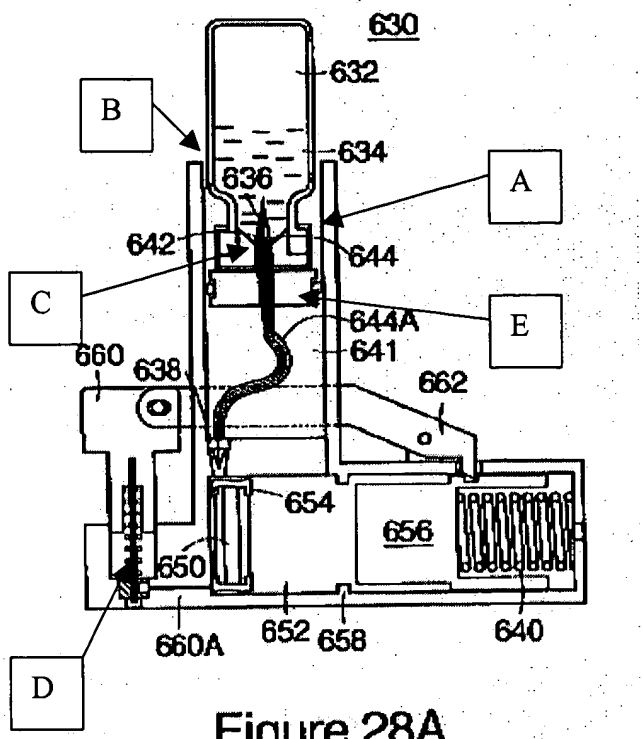

Figure 28A

2-Lavi et al. discloses a drug delivery system, as recited in Claims 19, 20, 22 and 23, comprising a vial (102) containing a quantity of medicinal fluid, wherein the vial comprises a container having a fixed rearward wall (A, see labeled Figure below) and a fixed pierceable wall (112) sealing the forward end; a holder (B, see labeled Figure below) configured to receive the vial; an injection needle (130-5) for expelling the medicinal fluid from the device wherein the injection needle comprises a sharpened tip operable between an extended position (shown in Figure 9E) in which the sharpened tip is exposed for use and a protected position (shown in Figure 9A) in which the sharpened tip is shielded to prevent inadvertent contact with the sharpened tip; and a communication path (250, C, see labeled Figure below) adapted to establish

fluid flow between the vial and the injection needle to allow the medicinal fluid to flow from the vial to the injection needle; wherein after use the needle is disposed in the protected position; and a seal (230, shown in Figure 9C) disposed along the communication path, wherein the seal is pierceable to allow medicinal fluid to flow along the communication path.

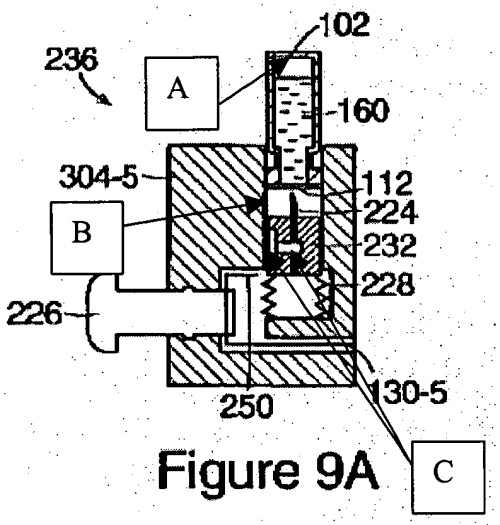

Figure 9A

3-Lavi et al. discloses a drug delivery system, as recited in Claims 19, 20 and 32, comprising a vial (500) containing a quantity of medicinal fluid, wherein the vial comprises a container having a fixed rearward wall (A, see labeled Figure below) and a fixed pierceable wall (B, see labeled Figure below) sealing the forward end; a holder (C, see labeled Figure below) configured to receive the vial; an injection needle (402, see Figure 20C-3) for expelling the medicinal fluid from the device wherein the injection needle comprises a sharpened tip operable between an extended position (shown in Figure 20C-3) in which the sharpened tip is exposed for use and a protected position (shown in Figure 20C-2) in which the sharpened tip is shielded to prevent inadvertent contact with the sharpened tip; and a communication path (E) adapted to establish fluid flow between the vial and the injection needle to allow the medicinal fluid to flow

pierceable wall (B, see labeled Figure below) sealing the forward end; a holder (C, see labeled Figure below) configured to receive the vial; an injection needle (664) for expelling the medicinal fluid from the device wherein the injection needle comprises a sharpened tip operable between an extended position (shown in Figure 28C) in which the sharpened tip is exposed for use and a protected position (shown in Figures 28A and 28B) in which the sharpened tip is shielded to prevent inadvertent contact with the sharpened tip; and a communication path (644, 644A, 652A) adapted to establish fluid flow between the vial and the injection needle to allow the medicinal fluid to flow from the vial to the injection needle; wherein after use the needle is disposed in the protected position; a biasing element (D, see labeled Figure below) biasing the needle toward the retracted position; a chamber (652) for receiving the medicinal fluid from the vial, wherein the medicinal fluid is subsequently expelled from the chamber though the injection needle; a conduit (644A) between the vial and the chamber; the chamber is disposed in a first housing (E, see labeled Figure below); a second housing (F, see labeled Figure below) associated with the injection needle, wherein the first housing is displaceable relative to the second housing; wherein displacing the first housing relative to the second housing operates to expel the medicinal fluid from the chamber through the injection needle; a stop (662) for releasably impeding relative displacement between the first and second housings; and comprising a means for pressurizing the vial (641, 642).

from the vial to the injection needle; wherein after use the needle is disposed in the protected position; a biasing element (419, see Figures 18A-18C) biasing the needle toward the retracted position.

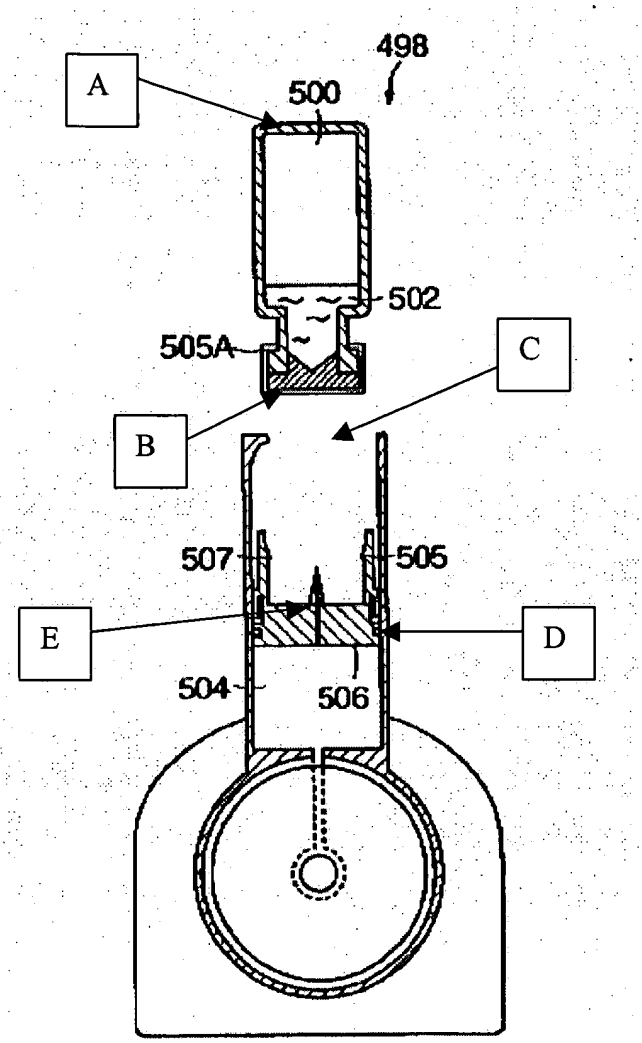

Figure 20A-1

4- Lavi et al. discloses a drug delivery system, as recited in Claims 19, 20, 24-26, 28-30 and 32, comprising a vial (632) containing a quantity of medicinal fluid, wherein the vial comprises a container having a fixed rearward wall (A, see labeled Figure below) and a fixed

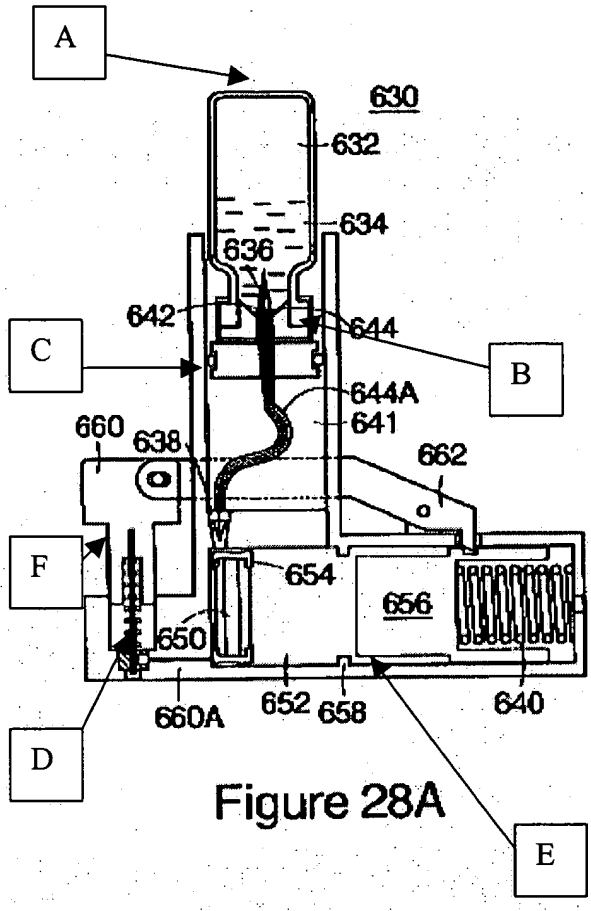

Figure 28A

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (US 5,199,949 A).

1-Haber et al. discloses a multiple pharmaceutical syringe, as recited in Claims 1, 2, 8, 11 and 13, comprising a hollow body (4); a socket (6, 8) associated with the body configured to receive the vial (30, 32); a needle (78) having a sharpened tip operable between an exposed position (shown in Figure 8) in which the sharpened tip projects forwardly from the body and a shielded position (shown in Figures 4-6 and 9) in which the sharpened tip is shielded from contact; and a transfer chamber (10) within the body for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle; wherein after use, the needle is disposed in the shielded position; a transfer conduit (70) configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber; a piston (26) for expelling medicine out of the transfer chamber through the needle; a valve (58, 59) adapted to control the flow of fluid between the transfer chamber and the vial; and a pierceable rear seal (36) adapted to provide a fluid-tight seal between the vial and the transfer chamber.

Haber et al. fails to disclose the hollow body in the form of a barrel.

It would have been obvious to one having ordinary skill in the art to have manufactured Haber et al.'s hollow body in the form of a cylinder, so as to streamline the design thus minimizing the bulk of the device and improving the user's ability to grip the device during use. Additionally, no criticality is given in Applicant's specification for forming the hollow body in the shape of a cylinder (i.e. barrel), thus the Examiner has deemed this limitation as a simple matter of obvious design choice, as the change in shape does not yield an improvement over the prior art device, see *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

2-Alternatively, with respect to Claims 1, 3 and 4, Haber et al. discloses a multiple pharmaceutical syringe, comprising a hollow body (4); a vial holder (6, 8) engaging the body and at least partially disposed within the barrel; a needle (78) having a sharpened tip operable between an exposed position (shown in Figure 8) in which the sharpened tip projects forwardly from the body and a shielded position (shown in Figures 4-6 and 9) in which the sharpened tip is shielded from contact; and a transfer chamber (10) within the body for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle; wherein after use, the needle is disposed in the shielded position; a transfer conduit (70) configured to extend between the vial and the transfer chamber for transferring medicine from the vial to the transfer chamber.

Haber et al. fails to disclose the hollow body in the form of a barrel.

It would have been obvious to one having ordinary skill in the art to have manufactured Haber et al.'s hollow body in the form of a cylinder, so as to streamline the design thus minimizing the bulk of the device and improving the user's ability to grip the device during use. Additionally, no criticality is given in Applicant's specification for forming the hollow body in the shape of a cylinder (i.e. barrel), thus the Examiner has deemed this limitation as a simple matter of obvious design choice, as the change in shape does not yield an improvement over the prior art device, see *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Allowable Subject Matter

Claims 5-7, 9, 12, 17, 21, 27, 55, 56, 58 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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